510(k) Summary

Proprietary Name:	AxSOS 3 Ti Locking Plate System Line Extension
Common Name:	Bone Screws
Classification Name and Reference:	Smooth or threaded metallic bone fixation fastener 21 CFR §888.3040
Regulatory Class:	Class II
Product Codes:	87 HWC: Screw, Fixation, Bone
Sponsor:	Stryker Trauma AG Bohnackerweg 1 CH-2545 Selzach Switzerland
Contact Person:	Elijah N. Wreh Regulatory Affairs Specialist 325 Corporate Drive Mahwah, NJ 07430 elijah.wreh@stryker.com Phone: 201-831-5691 Fax: 201-831-4691
Date Prepared:	November 8, 2013

Description

This Special 510(k) submission is being supplied to the U.S. FDA to introduce additional screw types and drive features to the currently marketed AxSOS 3 Ti Locking Plate System (K123964). The additional screw types will include: 3.5mm and 4.5mm Cortex Shaft screws, 4mm and 6mm Cancellous partially and fully threaded screws. The subject device is an internal fixation device that consists of monoaxial locking plates and various types of screws to fit different types of fractures in the tibia and femur. The subject device consists of anatomically contoured Femur and Tibia plates and various types of screws which were previously cleared in K123964. All components are manufactured from Titanium alloy per ASTM F136. The Distal Lateral Femur plates are fixed to the femur using 5mm locking screws or non-locking screws with either or

4.5mm Cortex and 6mm cancellous non-locking screws. The Proximal Lateral Tibia plates are fixed to the tibia using 4mm locking screws with either or 3.5mm Cortex and 4mm cancellous non-locking screws.

Intended Use

The AxSOS 3 Ti Locking Plate System Line Extension is intended for long bone fracture fixation.

Indications

The AxSOS 3 Ti Locking Plate System Line Extension is intended for long bone fracture fixation. Indications include:

- Diaphyseal, metaphyseal, epiphyseal, extra- and intra-articular fractures
- Non-unions and malunions
- Normal and osteopenic bone
- Osteotomies

Substantial Equivalency

The subject device components are substantially equivalent to the AxSOS 3 Ti Locking Plate System (K123964) and the Osteo BOS System (K972323, currently marketed as the Stryker Plating System) in regards to intended use, design, materials, and operational principles for use for long bone fracture fixation.

Non-Clinical Test

A risk analysis was performed according to the requirements of ISO 14971: "Medical Devices – Application of risk management of medical devices." The evaluation demonstrated that the subject device did not present a new worst case and that the same verification and validation methods were applied to the subject components in comparison to the previously cleared predicate devices (K123964 & K972323). The analyses demonstrated that the subject components met the performance requirements and are as safe and effective as the predicate devices.

Conclusion

The subject components of the AxSOS 3 Ti Locking Plate System Line Extension are substantially equivalent to the predicate devices identified throughout this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 18, 2013

Stryker Trauma AG
Mr. Elijah Wreh
Regulatory Affairs Specialist
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K133440
Trade/Device Name: AxSOS 3 Ti Locking Plate System (Line Extension)
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 21, 2013
Received: November 22, 2013

Dear Mr. Wreh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133440

Device Name: AxSOS 3 Ti Locking Plate System Line Extension

Indications for Use:

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Indications include:

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- Normal and osteopenic bone
- Osteotomies

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices